

REMARKS

Claims 1-34 have been cancelled in the present application. Claims 35-52 have been newly introduced. No new matter has been added by virtue of this amendment. Basis for this amendment can be found at pages 10 and 11 or the present specification.

35 USC §112

The Examiner has rejected claims 2 as being indefinite under 35 USC §112, second paragraph. In light of the above introduced amendments, Applicant believes that this rejection has been rendered moot.

35 USC §103

The Examiner rejects claims 1, 2, 4, 5, 7-11, 13-15, 17, 22-24 and 26-31 under 35 USC §103(a) as being rendered obvious by Muhammad (US 5, 167,964) in view of Santus (US 6,280,761). The Examiner also rejects claims 12, 19-21 and 25 under 35 USC §103(a) as being obvious in light of Muhammad in view of Santus and/or Rapp (US 6,180,143) and/or Burnick (US 2003/0017202).

Generally, Applicants contend that Muhammad in combination with Santus, even when considered in light of Rapp and/or Burnick, does not achieve the claims as herein amended. Applicant asserts that each and every element is not taught or suggested to one of skill in the art by a reading of the references.

Muhammad relates to a semi-enteric drug delivery system which comprises an inert core, a first coating layer over the core which comprises a medicament and a second coating layer over the first coating layer comprising a mixture of methacrylic acid copolymer (type C) and povidone in a range of particular ratios. See Muhammad at abstract. These semi-enteric drug delivery systems may be incorporated within hard or soft confectionery compositions, however, there is no teaching in Muhammad as to how this is achieved.

The present claims, as amended, are directed to a "non-hygroscopic, glassy lozenge useful for transmucosal, oral administration of a nicotine active, comprising a glassy matrix base comprising isomalt; from about 0.5 mg to about 5 mg of a

nicotine active; and one or more water soluble gelling gums in an amount sufficient to provide an oral dissolution rate of said glassy matrix such that at least 80% of the nicotine active is absorbed via the oral mucosa" and prepared by the process claimed. Applicants contend that Muhammad does not teach such a lozenge prepared by the process claimed as Muhammad does not teach a method of making a glassy lozenge at all.

The Examiner relies on Santus for the proposition that various types of nicotine are known in the art and that a nicotine lozenge may be useful for smoking cessation. Further, the Examiner indicates that the claimed nicotine content is contemplated by Santus. Applicants agree that Santus teaches a nicotine lozenge and indicates methods such as compression and encapsulation, among others, as examples of suitable methods of manufacture. There is no teaching in Santus of a glassy matrix lozenge prepared by the process of the present claims. Santus, indicates, in fact that direct compression is the preferred method of manufacture of the nicotine lozenges taught therein. Thus, it cannot be said that Santus in combination with Muhammad renders the present claims obvious.

The Examiner relies on Rapp and Burnick for the principle that sweetening agents, such as Isomalt, are known for use in nicotine formulations. Rapp relates to chewing gum compositions which may comprise 1,1-GPS alons or in combination with other sweeteners. Such sweeteners are incorporated into the Rapp formulations to increase flexibility of the gum and prevent drying out of the gum during storage. Burnick relates to an oral dosage form comprising a soft core encased within a brittle shell coating that may also include sweeteners of the type described above.

Again, neither Rapp nor Burnick relates to a non-hygroscopic, glassy lozenge formulation and thus cannot be said to teach such a lozenge prepared by the claimed method. Thus, the combination of either or both of these references with Muhammad and Santus does not result in the present invention.

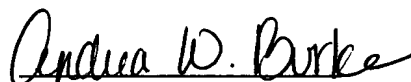
No combination of the cited references teaches a non-hygroscopic glassy lozenge comprising at least isomalt, a nicotine active and one or more water soluble gelling gums prepared in the manner described. Although the patentability of

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product by process claims is determined by the patentability of the product itself, where a manufacturing process would be expected to impart distinctive structural characteristics to the final product, the structure implied by those process steps should be considered. *See MPEP §2113*. In the instant invention, the structure implied by the process steps is a lozenge comprising a glassy, amorphous matrix wherein the nicotine active is substantially contained within the glassy matrix. *See specification, page 5, lines 29-31*. This structure is not contemplated by Muhammad in combination with Santus, Rapp and/or Burnick.

In light of the amendments submitted herewith and the accompanying remarks, Applicants believe that all objections and rejections raised by the Examiner have been addressed. Thus, Applicants respectfully request withdrawal of the rejections under 35 USC §112 and §103 and allowance of all claims that remain pending.

Respectfully submitted,



Andrea W. Burke
Attorney for Applicants
Registration No. 48,586

GLAXOSMITHKLINE
Corporate Intellectual Property-UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Tel: 610 270 7513; Fax: 610 270 5090
Email: Andrea.W.Burke@gsk.com
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